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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/809.621	06/02/97	IDA	N 599-158P

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EXAMINER
SUN-HOFFMAN, L

ART UNIT
1642

PAPER NUMBER

DATE MAILED: 06/10/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/809,621

Applicant(s)
Ida et al

Examiner
Lin Sun-Hoffman

Group Art Unit
1642



☒ Responsive to communication(s) filed on Mar 24, 1998

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 7 and 9-12 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 7 and 9-12 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

1. Claims 7, 9-12 are pending for the examination.
2. Rejections under 35 U.S.C. 112, first and second and fourth paragraph are withdrawn.
3. Rejection to claims 1-6 under 35 U.S.C. 102(b) over Gomi et al or Michalevicz is withdrawn.

Rejection maintained

Claim Rejections - 35 U.S.C. § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 7, 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Gomi et al or Modi (US Patent Number 5417982).

Claim 7 is drawn to a method for a treating bone disorder comprising administering an effective bone treating amount of an interferon beta or an interferon inducer to a patient suffering from said bone disorder.

Claims 9-11 further limit claim 7 in reciting a naturally occurring or recombinant interferon beta; that interferon inducer is interferon alpha, beta or gamma; and the various of bone disorder including osteoporosis.

Gomi et al teach a method of using IFN-beta to treat human osteosarcoma (see abstract). Applicants argue that osteosarcoma means a tumor originating from bone tissue, and it does not

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mean a tumor-related bone disorder. However, osteosarcoma is a bone disorder as claimed in claim 7. Moreover, an osteosarcoma is inherently a tumor-related bone disorder. Therefore, the argument is found unpersuasive.

6. Modi et al teach a method of treating osteoporosis by interferon beta (see column 4, lines 62-68).

Claim Rejections - 35 U.S.C. § 103

7. Claims, 7, 9-12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gomi et al.

Claim 12 further limits claim 7 in reciting that the bone disorder is a bone metastasis from mammary carcinoma, lung cancer, prostate cancer, thyroid gland carcinoma, renal cancer, colon cancer, cancer of the digestive tract, and cancer of the esophagus.

Gomi et al teach as described above. However, Gomi et al differ from instant invention in failing to disclose a bone disorder which is a bone metastasis from other tumors. Applicants admit in Background art section that bone formation and resorption is disturbed including cancer-related diseases such as bone metastasises of lung cancer, mammary carcinoma or renal cancer (see page 2 last paragraph to page 3 first paragraph of specification).

It would have been *prima facie* obvious for one of the ordinary skill in the art at the time the invention was made to use the method of treating bone disorder disclosed by Gomi et al. One of ordinary skill in the art would have been motivated to substitute treatment of bone metastasises from various cancers for Gomi et al's treatment of osteosarcoma by IFN-beta because one of ordinary skill in the art would have recognized that IFN beta would function in the same manner on all bone related tumor cells in providing a treatment of a bone disorder.

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Conclusion

8. No claim is allowed.
9. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lin Sun-Hoffman, Ph.D., whose telephone number is (703)-308-7552. The examiner can normally be reached on Monday to Friday from 7:30 am to 4:00 pm Eastern Standard Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) -308-2731.

Lin Sun-Hoffman, Ph.D.

SLH

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June 9, 1998

A handwritten signature in black ink, appearing to read 'Lila Feisee', with a long horizontal stroke extending to the right.

**LILA FEISEE
SUPERVISORY PATENT EXAMINER**